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In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Qui, et al.	EXAMINER: not yet assigned
SERIAL NO.: 09/877,681	ART UNIT: 1615
FILING DATE: June 8, 2001	DOCKET NO.: 6437.US.P4
TITLE: <b>CONTROLLED RELEASE FORMULATION OF DIVALPROEX SODIUM</b>	I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Assistant Commissioner for Patents, Washington, D.C., 20231 on the date shown below. <i>Sarah Mayhew</i> 09/20/01 Sarah Mayhew Date

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

In accordance with their duty of disclosure under 37 C.F.R. §1.56, and as authorized and encouraged under 37 C.F.R. §§ 1.97-1.98 and the provisions of MPEP §§ 609 and 707.05(b), Applicants submit herewith certain patent documents, publications and/or other information ("references") which the Patent and Trademark Office may wish to consider in examining the above-identified patent application. The identification of any reference herein is not intended to be and should not be understood as being an admission that such reference necessarily constitutes "prior art" within the meaning of applicable law.

The cited references are listed on attached form PTO-1449.

- ☒ A copy of each cited reference is provided;
- ☐ Copies of cited references are not provided because each has previously been made of record in the parent application, or is otherwise known to be in the Examiner's possession.

The Examiner is requested to review and evaluate each cited reference to make an independent assessment of the materiality of each, if any, to the examination of the above-identified application. The Examiner is requested to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the present invention. The copies being submitted with this Statement are the best copies available at this time. Applicants respectfully request that (1) the references cited herein be made of record; (2) that the Examiner acknowledge his consideration of each reference by initialing and returning the enclosed copy of the PTO-1449 form; and (3) that such references appear on the printed patent as having been considered on the record.

With regard to payment of a fee:

- ☒ No fee is due because:
- ☒ This Statement is mailed within three months of the filing date of this application, or before the mailing date of a first office action on the merits (see 37 C.F.R. §1.97(b)).
- ☐ Applicants certify that each reference cited in this Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. (see 37 C.F.R. §1.97(e)).
- ☐ This Statement is filed after the mailing date of a first Office Action on the merits but before the mailing date of either a final action or a Notice of Allowance (see 37 C.F.R. §1.97(c)) so a fee of **\$180.00** is specified by 37 C.F.R. §1.17(p).


If any fees are owed, or any credit is due pertaining to this case, please charge that fee or apply that credit to Deposit Account No. 01-0025. A duplicate sheet of this page is enclosed.

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Docket : 6437.US.P4

Respectfully submitted,

  
by J. Michael Dixon  
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Sheet 1 of 1

FORM PTO-1449 U.S. Department of Commerce  
(Rev. 2032) Patent and Trademark Office

SEP 24 2001

Atty. Docket No.: 6437.US.P4

Serial No. 097/877,681

1600/2900

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTApplicant  
Qui, et al.

(Use several sheets if necessary)

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## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)

## FOREIGN PATENT DOCUMENTS

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

			Colins, et al., "Depakote CR: Biopharmaceutical and Pharmacokinetic Studies of a New Formulation for Once Daily Dosing", Neurology, Vol. 50(4), Supplement 4, April 1998, p. A426
			Samara, et al., "Bioavailability of a Controlled Release Formulation of Depakote", No. 3.053, Epilepsia, Vol. 38, Suppl. 8, 1997
			Cavanaugh, et al., "Effect of Food on the Bioavailability of a Controlled Release Formulation of Depakote Under Multiple Dose Conditions", No. 2.002, Epilepsia, Vol. 38, Suppl. 8, 1997

EXAMINER

DATE CONSIDERED ☐

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.